c) a nucleotide sequence encoding the polypeptide linker is formed by two partially overlapping PCR primers during a PCR reaction that links the first variable domain and the second variable domain; and wherein

d) the compound has a monovalent, bivalent, or multivalent structure.

REMARKS

With entry of this Amendment, claims 1-13 and 25-34 are under consideration. Applicants have introduced new claim 34 to include a compound with one antigen binding site. Support for this claim may be found in the specification's original claims, at page 2, lines 21-30 and in Examples 1-3. Thus, claim 34 does not introduce new matter. Applicants now respond to each of the current rejections according to its statutory origin.

Rejections Under 35 U.S.C. §112

Applicants wish to thank the Office for withdrawing its new matter and enablement rejections of claims 1-13 and 25-33 under 35 U.S.C. §112, first paragraph. Applicants address the maintained rejection of claim 5 and the new rejection of claims 1-13 and 25-33 below.

The Office maintains its rejection of claim 5 under 35 U.S.C. §112, first paragraph, as not enabled because Applicants have allegedly not shown that the hybridoma that expresses the L6 monoclonal antibody (MAb) was publicly available. Applicants previously cited two articles by Hellström et al., one of which was published in the Proceedings of the National Academy of Sciences (PNAS), to demonstrate that

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the L6 MAb was publicly available. The Office then noted that there was no evidence to show that the journals in which the Hellström articles were published had a policy requiring authors to share reagents with the public. To satisfy this request, Applicants submitted a printout of a portion of the PNAS web site that clearly indicated that authors must make "unique materials (e.g., cloned DNAs, antibodies, . . .) promptly available on request by qualified researchers . . . ."

In the current Office Action, the Office raises two issues. First, it notes that the printout was revised in May 2002. As such, the Office contends that it does not prove that the policy discussed above was in effect at the time of filing. To show that at the time of filing, December 12, 1997, PNAS required authors to make unique reagents publicly available, Applicants submit a copy of the journal's author instructions from a 1997 issue of PNAS. *See* page xi, section viii under Journal Policies. Thus, PNAS authors were required to make unique reagents available to the public at the time the instant application was filed.

Second, the Office alleges that PNAS requires that only the antibodies be provided, not the hybridoma. Applicants contend that the L6 hybridoma is not necessary for practicing the invention. Rather, the skilled artisan only needs the L6 MAb to identify the antigen recited in claim 5. As long as a skilled artisan can gain access to the L6 MAb, she can use the invention. Given that PNAS authors must provide antibodies that are used in their papers, this tool for practicing the invention is publicly available. *Arguendo*, even if the hybridomas were necessary, Applicants note that antibodies are listed in the PNAS policy as part of a non-exhaustive list that provides examples of unique materials. Hybridomas are also unique materials due to

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their genetic content. Applicants respectfully request that the Office withdraw its rejection of claim 5.

Claims 1-13 and 25-33 stand rejected 35 U.S.C. §112, second paragraph, as allegedly indefinite. Specifically, the Office believes that claim 1 is confusing because parts a) and b) of the claim refer to polypeptide chains while part c) refers to a nucleotide sequence. The Office then asserts that part c) cannot be properly cited as being a component or feature of the claimed compound.

Applicants assert that part b) of claim 1 provides a description of the compound's polypeptide chain, which includes a polypeptide linker. Part c) further describes the polypeptide linker of part b) in terms of how it is formed at the nucleotide level by overlapping PCR primers during a PCR reaction. Thus, part c) should be read in combination with parts a) and b) as descriptive features of the claimed compound. Applicants request that the Office withdraw its rejection in light of this clarification.

Rejections Under 35 U.S.C. §102

Claims 1-4, 8, 9, 25, 26, and 33 remain rejected under 35 U.S.C. §102(e) as allegedly anticipated by Winter et al. (U.S. Patent 6,248,516; "Winter"). According to the Office, all the alleged prior art need teach is a linking polypeptide, regardless of how it was formed, because claim 1 recites a polypeptide having a polypeptide linker. The Office is not taking into consideration the fact that the polypeptide linker is encoded by a nucleotide sequence formed during a PCR reaction.

Applicants assert that part c) of claim 1 provides a meaningful description of the polypeptide linker and as such should not be dismissed. The Office considers the

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compound of claim 1 without acknowledging the process described by step c) in the claim. See the current Office Action at p. 6. The Court of Appeals for the Federal has reasoned that one must construe the product of the pending claims in the context of the process used to generate that product. *See Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 23 U.S.P.Q.2d 1482 (Fed. Cir. 1992). This decision has been followed in a lower court as well. *See Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7, 27 U.S.P.Q.2d 1475 (Mass. Dist. Ct. 1993). Moreover, construing product-by-process claims as pure product claims, in the absence of any process step, is contrary to claim construction principles. *See Sage Prod., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 44 U.S.P.Q.2d 1103 (Fed. Cir. 1997).

Thus, to construe the pending compound claims without regard to the process step ignores the Applicants' inventive step in producing the claimed compound by linker formation during the PCR reaction. As Applicants noted in the prior response, Winter does not discuss a polypeptide linker that is ultimately produced by overlapping PCR primers. Applicants respectfully request that the rejection of claims 1-4, 8, 9, 25, 26, and 33 under 35 U.S.C. §102(e) be withdrawn.

Rejections Under 35 U.S.C. §103

The rejections under § 103(a) may be separated into two groups: 1. those that center around the Bosslet et al. (*Brit. J. Can.* 65:235 (1992); "Bosslet"); Seemann et al. (Canadian Patent 2,062,047; "Seemann"); and Huston et al. (U.S. Pat. 5,132,405; "Huston") references; and 2. those that center around the Winter reference. Applicants address these rejections according to their group below.

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Rejections based on Bosslet, Seemann, and Huston

Claims 1-9, 25-27, 30, and 33 remain rejected under 35 U.S.C. §103(a) as allegedly obvious over Bosslet or Seemann in view of Huston, Bosslet et al. (U.S. Pat. 5,591,828: "Bosslet 2"), and Eaton et al. (EP 392,745; "Eaton"). According to the Office, Bosslet and Seemann both teach a fusion protein comprising a Fab, a linker, and a human β-glucuronidase. The Office acknowledges that an Fab fragment is different from a sFv. Huston also allegedly teaches that antigen binding regions may be present in multiple copies and that they may be fused to other molecules such as enzymes. The Office also relies on Huston for the proposition that expression of these proteins in eukaryotic cells would lead to protein glycosylation. The Office also alleges that Eaton teaches that sFv fragments may be used in conjugates containing prodrug enzymes. *See* Office Action of June 7, 2001 at pp. 5 and 6.

In the prior response, Applicants noted that the Office presented conflicting rejections of the claimed invention. On one hand, the Office rejected claims 1-13 and 25-33 under 35 U.S.C. §112, first paragraph, because, according to the Office, one could not provide the internal linkers without undue experimentation. On the other hand, the Office rejected a substantial portion of these claims as obvious. The Office independently asserted that sFv and Fab fragments were functionally equivalent and thus it would be obvious to substitute sFv fragments into Bosslet and Seemann's constructs. An invention cannot require undue experimentation and be obvious at the same time. The Office responded to Applicants' argument by withdrawing its rejection under §112, first paragraph, and in doing so it believes that it has rendered our argument moot. Applicants do not agree.

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Whether or not the Office withdraws that rejection, the fact remains that it believed that generating the linkers of the invention would require undue experimentation. As noted above, the Office reasons that because sFv fragments and Fab fragments are *functionally* equivalent, it would be obvious to substitute sFv fragments into the constructs of Bosslet and Seemann. Applicants noted in the prior response that even if an Fab fragment and an sFv fragment were functionally equivalent, they are by no means structurally equivalent. Specifically, an Fab fragment has two separate chains whereas an sFv fragment is a single chain. As discussed above, the Office has agreed that Fab fragments and sFv fragments are structurally different. *See* Office Action of June 7, 2001, Paper 20, p. 4, line 20 to p. 5, line 3. Claim 1 describes the structural attributes of the claimed compound. Thus, the Office is making an incorrect comparison when it tries to base its obviousness rejection on alleged functional equivalents.

Applicants also previously argued that Bosslet, Seemann, and Huston demonstrate a lack of consensus as to whether a single polypeptide chain should be used to express the antigen binding site. Specifically, Seemann and Bosslet both suggest that the tumor binding portion of the construct should be as similar to the original antibody as possible. Huston, in contrast, teaches toward a single polypeptide chain to form the antigen binding portion. The Office responded by asserting that Applicants considered the teachings of these references in isolation. This is not correct, as Applicants considered the teachings of the these references as a whole to show that in the field, as a whole, there was confusion on this issue.

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Applicants also note that when the Office had asserted that "since Huston et al. teach that antibodies can be engineered to provide sFv constructs with[in] antigen binding activity, there is no reason to consider that Seemann . . . or Bosslet teach away from forming sFv . . . constructs," it improperly imported the teaching of one reference into another. *See* Office Action of January 22, 2002, Paper 24, p. 6, line 19 to p. 7, line 2. Each reference stands independently for what it teaches and it is the combination of these references that does or does not support obviousness.

Moreover, Applicants noted in the previous response that the specification teaches that the enzyme may be fused to the antigen binding domain by chemical means. Thus, even if Huston teaches that the sFv may be fused to an enzyme, as the Office believes this reference does, the skilled artisan would not have readily considered putting the enzyme on the same polypeptide chain. The Office responded by indicating that Huston's teaching that the sFv may be fused to an enzyme is sufficient in light of the "well understood" definition of a fusion polypeptide. Applicants respectfully traverse the Office's conclusion for the following reason.

A fusion polypeptide does not necessarily mean that a single strand of nucleic acid encodes a polypeptide having different functions. For example, both Bosslet and Seemann call their Fab constructs "fusion proteins" and in each instance the fusion protein was expressed by two separate nucleic acids, one of which contained the variable region from the heavy chain with the other containing the variable region of the light chain. Thus, the Office has again read its own knowledge and assumptions regarding the art into the teaching of the reference.

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The Office also asserts that it is "merely rely[ing] upon well known scientific knowledge in the pertinent field" in arriving at its rejections. *See* current Office Action at p. 5, lines 17-18. The Office further contends that this type of reasoning does not contradict the holding of *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002). Applicants disagree. The Office's reliance on "well known scientific knowledge" or common knowledge is exactly what the Federal Circuit has warned against. In *Lee*, the Court noted that

> [The] factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority . . . . Deferential judicial review under the Administration Procedure Act does not relieve the agency of its obligation to develop an evidentiary basis for its findings. * * * Conclusory statements such as those here provided do not fulfill the agency's obligation . . . . "Common knowledge and common sense," even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority. . . . The board . . . must set forth the rationale on which it relies.

Id. at 1344-45. *See also, In re Zurko*, 258 F.3d 1379 (Fed. Cir. 2001) (deficiencies of references cannot be saved by appeals to "common sense" and "basic knowledge" without any evidentiary support.). As discussed above, the Office is making use of his general knowledge in the art to compensate for the shortcomings of the references cited against the pending claims.

The Office believes that Eaton teaches that sFv fragments may be conjugated to prodrug enzymes. The Office's reading of this reference is not accurate. Specifically, Eaton discusses "Fv" fragments and defines them at page 7, line 54 to page 8, line 1 as follows:

> [T]he DNA encoding the heavy (H) chain of an antibody (or a fragment of the H chain bearing the antigen combining site)

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> may be ligated to the DNA sequence encoding the β-lactamase or fragment thereof. The resulting H chain-enzyme hybrid may then be expressed and secreted from transformed mammalian or microbial cells in culture together with the appropriate light (L) chain (or L chain fragment). The expressed antibody H chain-enzyme hybrid associates with the expressed L chain to form a functional Fv, Fab, or full length HL antibody . . . .

Thus, an "Fv" as defined in Eaton consists of two separate chains, an H chain hybrid and a separate L chain. This is not consistent with a single chain expressing both H and L variable regions. Thus, Eaton does not teach conjugation to an sFv, as the Office believes.

Applicants note that the above arguments that address Bosslet, Seemann, and Huston apply to all the rejections in this section, which center on a combination of these three references. Applicants provide below additional arguments as they relate to the specific combination of additional references set forth for the remaining rejections in this section.

Claims 1, 2, 9, 11, 12, 31, and 32 are rejected as allegedly obvious over Bosslet or Seemann in view of Huston, Bosslet 2, Eaton, and in further view of Ong et al. (*Can. Res.* 51:619 (1991); "Ong"), Bagshawe et al. (WO 89/10140; "Bagshawe") and Huston et al. (*Meth. Enz.* 204:46 (1991); "Huston 2"). According to the Office, Huston teaches that polypeptides containing sFv may be secreted into the periplasmic space of Gram-negative bacteria, such as *E. coli*. The Office then independently asserts that *E. coli* are easier to grow than eukaryotic cells such as myeloma cells. On that assertion, the Office concludes that one would have been motivated to use *E. coli* to produce correctly folded proteins in large amounts. Ong allegedly teaches that it is advantageous to glycosylate antibodies to permit rapid clearance. The Office also relies on Bagshawe

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for a similar teaching. The Office then concludes that because antibody-enzyme conjugates are functionally equivalent to sFv-enzyme proteins, it would be obvious to glycosylate sFv-enzyme fusion proteins. *See* Office Action of June 7, 2001 at pp. 7-9.

As discussed above, the Office's independent assertion that *E. coli* are allegedly easier to grow than eukaryotic cells has not been supported by authority. Again, the Office is violating the tenet of *In re Lee*. Thus, the Office's conclusion that one would have been motivated to use *E. coli* to produce the claimed compound is without merit. Regarding Ong, the Office is using an inappropriate comparison on several levels. First, Ong focuses on producing galactose conjugates of whole antibodies. Ong does not teach antibody-enzyme conjugates. Second, antibodies conjugated to galactose are not functionally equivalent to an sFv fragment linked to a pro-drug activating enzyme, as Ong's constructs do not contain enzymes. Third, *arguendo*, even if they were functionally equivalent, this is not the appropriate comparison to make. The compound of claim 1 is defined by its structure, not function. Ong does not contemplate the structure described in claim 1 and there is no way to know from Ong's teaching whether glycosylation would work with the structure described in claim 1. Such uncertainty is manifest in the fact that Ong tested the other biological functions of the galactose-conjugated antibodies (i.e., complement-mediated cytotoxicity and cell-mediated cytotoxicity) to be sure that galactose conjugation did not affect these functions. *See* Ong at p. 1620, right column. The inventors of the claimed invention, however, have shown that glycosylation is in fact possible with the compound of claim 1.

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Bagshawe conjugates enzymes to whole antibodies or to Fab fragments (see p. 20), but does not teach conjugating an enzyme to an sFv fragment, which is a different structure. And neither Bagshawe nor Ong provide a motivation to glycosylate the compound of claim 1. Though Huston 2 does discuss sFv fragments in the context of fusion proteins, Huston 2 does not teach an sFv fragment in which the linker is produced during the PCR reaction nor does this reference suggest glycosylating such a protein. Thus, Bosslet, Seemann, Huston, Bosslet 2, Eaton, Ong, Bagshawe, and Huston 2 alone or in combination cannot make the invention of claims 1, 2, 9, 11, 12, 31, and 32 obvious. In sum, these references do not provide the requisite teaching nor motivation to make the claimed invention. Applicants respectfully request that the Office withdraw this rejection.

The Office maintains its rejection of claims 1, 10, 13, and 29 under 35 U.S.C. §103(a) as allegedly obvious over Bosslet or Seemann in view of Huston, Bosslet 2, Bagshawe, Huston 2, and in further view of Goochee et al. (*Biotechnol.* 9:1347 (1991); "Goochee"). According to the Office, Goochee shows that yeast could express a polypeptide having a high degree of mannosylation, which would facilitate rapid clearance. The Office concludes that it would have been obvious to produce a polypeptide with mannose moieties to provide rapid clearing of the polypeptide. See Office Action of June 7, 2001 at pp. 9 and 10. Applicants refer to the arguments above regarding Bosslet, Seemann, Bosslet 2, Bagshawe, and Huston 2, while addressing Goochee below.

Goochee provides a general discussion about oligosaccharide structures in proteins produced by mammal cells, yeast cells, insect cells, and plant cells. Though

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Goochee does teach that yeast express mannosylated proteins and that mannosylation proteins are rapidly cleared from the host via the liver and macrophage, there is no suggestion nor motivation to apply this to antibodies in particular let alone the sFv/enzyme complex described in claim 1. Goochee discusses antibodies only in the context of their recognizing epitopes blocked by oligosaccharides and antibodies that recognize the oligosaccharide moiety itself. A general observation that yeast can mannosylate proteins and that these proteins may be cleared from the blood quickly does not motivate one to use yeast in the specific application of expressing the sFv/enzyme complex of claim 1. Applicants therefore request that the Office withdraw its rejection.

The Office maintains its rejection of claims 1, 6, and 28 under 35 U.S.C. §103(a) as allegedly obvious over Bosslet or Seemann in view of Huston, Bosslet 2, Eaton, and in further view of Bagshawe et al. (WO 88/07378; "Bagshawe 2"). The Office believes that Bagshawe 2 provides that it was known and conventional to provide carboxypeptidase G2 from *Pseudomonas* as a prodrug activating enzyme. *See* Office Action of June 7, 2001 at p. 10. Applicants refer to the arguments above regarding Bosslet, Seemann, Huston, Bosslet 2, and Eaton, while addressing Bagshawe 2 below.

Bagshawe 2 discusses antibody or antibody fragment/enzyme proteins. But antibody fragments are defined as $F(ab)_2$ or $F(ab)_1$ fragments and not sFv fragments. *See* p. 7, lines 2-6 and p. 8, lines 9-12. Thus, this reference does not provide the motivation to use carboxypeptidase G2 in concert with the structure of an sFv fragment. Further, none of the other references used in this rejection teach carboxypeptidase G2 and also fail to provide a motivation for this combination.

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Rejections based on Winter

The Office maintains its rejections of the pending claims under 35 U.S.C. §103(a) in view of Winter and a combination of other references. These rejections are as follows:

1. Claims 1, 2, 4, 5, 7, and 9 remain rejected as allegedly obvious in light of Winter and in further view of Seemann. Specifically, the Office believes that Seemann teaches therapeutic fusion proteins with binding specificity to CEA and that have β-glucuronidase activity. The Office then asserts that CEA is a known tumor antigen and β-glucuronidase is a known pro-drug activating enzyme and concludes that it would have been obvious to combine these activities with Winter's single domain ligand constructs. The Office also asserts that expression of proteins in BHK cells would "inherently" result in glycosylation. *See* Office Action of January 22, 2002 at pp. 10 and 11.
2. Claims 1, 6, 27, and 30 remain rejected as allegedly obvious in light of Winter in view of Eaton. Specifically, the Office contends that while Winter does not teach β-lactamase as a pro-drug activating enzyme, Eaton teaches that such enzymes were known in the art in the context of antibody conjugates.
3. Claims 1, 6, and 28 remain rejected as allegedly obvious in light of Winter in view of Bagshawe 2. According to the Office, Winter does not teach carboxypeptidase G2 as a pro-drug activating enzyme but Bagshawe 2 demonstrates that this enzyme was a known pro-drug activating enzyme.

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Thus, the Office believes that it would be obvious to use this enzyme in the context of Winter's single domain ligand constructs.

4. Claims 1, 10, 13, and 29 remain rejected as allegedly obvious in light of Winter in view of Ong and Bagshawe and in further view of Goochee. The Office uses Ong and Bagshawe as described above for claims 1, 2, 9, 11, 12, 31, and 32. He further believes that Goochee shows that yeast can express mannosylated proteins that are rapidly cleared thus making it obvious to express the polypeptide of claim 1 in yeast to attain mannosylation and rapid clearance. The Office also asserts that Goochee particularly teaches the proteins of claims 10 and 13 and that, even though claim 29 is not covered, the skilled artisan would have been able to determine which yeast strains would have been appropriate.

As Applicants discussed above with respect to the rejection based on Winter under 35 U.S.C. § 102(e), the Office considers the compound of claim 1 without acknowledging the process described by step c) in the claim. The Federal Circuit has reasoned that this is not the correct interpretation. *See Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 23 U.S.P.Q.2d 1482 (Fed. Cir. 1992); *Sage Prod., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 44 U.S.P.Q.2d 1103 (Fed. Cir. 1997). Thus, step c) should be considered as meaningful part of claim 1. Winter does not discuss a polypeptide linker that is ultimately produced by overlapping PCR primers nor do the other references cited in the four rejections based on Winter.

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In addition, as discussed above, Applicants note that Goochee's general teaching of expression of proteins in yeast does not provide motivation for expressing

the compound of claim 1 in yeast. Moreover, neither Winter, Ong, nor Bagshawe teach expression of their fusion proteins in yeast. Thus, none of the references cited in the fourth rejection above provide the necessary motivation.

For these reasons, Applicants request that the Office withdraw its rejections of claims 1, 2, 4-7, 9, 10, 13, and 27-30 under 35 U.S.C. §103(a).

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: March 7, 2003

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